SEP - 4 2003

K031785

ADMINISTRATIVE INFORMATION

Manufacturer Name:
MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact:
Kenneth K. Kleinhenz
Director of Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Intracardiac Patch

Trade/Proprietary Name: MacroPore Cardio-Wrap (TS)

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 870.3470, an Intracardiac Patch is a fabric device intended to be placed in the heart for use to repair septal defects, for patch grafting, and to repair tissue These devices are classified as Class II. Intracardiac Patches have been assigned Product Code DXZ.

INTENDED USE

The MacroPore Cardio-Wrap (TS) is indicated for use as a pericardium replacement device in patients that may require re-operation within six months.

DEVICE DESCRIPTION

Design Characteristics

MacroPore Cardio-Wrap (TS) is a resorbable implant in sheet form manufactured from poly lactic acid (PLA). MacroPore Cardio-Wrap (TS) can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore Cardio-Wrap (TS) to the desired shape or size. MacroPore Cardio-Wrap (TS) Sheet is fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. The MacroPore Cardio-Wrap (TS) can be used either alone or in conjunction with soft tissue fixation devices such as resorbable sutures, which can also serve to fixate the MacroPore Cardio-Wrap (TS) and prevent dislocation. The MacroPore Cardio-Wrap (TS) may be used in conjunction with various MacroPore manual instruments.

MacroPore Cardio-Wrap (TS) is provided in various shapes such as rectangles, ovals, and circles and will be provided in other shapes and sizes as needed for particular surgical procedures. MacroPore Cardio-Wrap (TS) is provided in sheets of 10mm x 10mm to 500mm x 500mm and will be provided in other shapes and sizes as needed for particular surgical procedures. The thickness of the MacroPore Cardio-Wrap (TS) ranges from 0.05 mm to 1.0 mm according to the region to be treated. The MacroPore Cardio-Wrap (TS) is provided in solid sheets. The borders of the sheets may be aligned with holes to attach suture material.

Material Composition

The MacroPore Cardio-Wrap (TS) is fabricated from polylactic acid (PLA).

In Vitro Testing

The MacroPore Cardio-Wrap (TS) is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures. Therefore, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. The relatively brief exposure anticipated during the surgical preparation of MacroPore Cardio-Wrap (TS) is not expected to have a significant effect on its mechanical properties.

Aging testing was performed on MacroPore Cardio-Wrap (TS). Testing demonstrated that the MacroPore Cardio-Wrap (TS) is strong enough for the indications for use.

Mechanical testing was performed on the MacroPore Cardio-Wrap (TS) which determined the MacroPore Cardio-Wrap (TS) to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

In Vivo Testing
An animal study was conducted to demonstrate safety and efficacy of the MacroPore Cardio-Wrap (TS) material. The animal studies demonstrated that the MacroPore Cardio-Wrap (TS) materials are safe and efficacious for the indications for use.

EQUIVALENCE TO MARKETED PRODUCT

The MacroPore Cardio-Wrap (TS) shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: Bio-Vascular Supple Peri-Guard, Sulzer Carbomedics Cardio Fix, and W.L. Gore Preclude Pericardial Membrane; Class II medical devices that were cleared for marketing in the United States under K983602 , K993288, and K012098, respectively.

Indications For Use
The MacroPore Cardio-Wrap (TS) shares identical indications for use principles with the predicate devices as both the MacroPore Cardio-Wrap (TS) and the predicate devices are indicated for the same surgical procedures.

Design and Materials
The physical designs of MacroPore Cardio-Wrap (TS) and the predicate devices (Bio-Vascular Supple Peri-Guard, Sulzer Carbomedics Cardio Fix, and W.L. Gore Preclude Pericardial Membrane) are substantially equivalent, consisting of thin semi-rigid sheets. The MacroPore Cardio-Wrap (TS) and the predicates also share design features of allowing for contouring. The MacroPore Cardio-Wrap (TS) is fully contourable when heated to approximately 55°C. The thickness of the predicate devices and the MacroPore Cardio-Wrap (TS) are substantially equivalent as the thinnest MacroPore Cardio-Wrap (TS) thickness is virtually identical to the predicate (0.5mm vs 1.0mm). The dimensions of the predicate devices are also comparable to the MacroPore Cardio-Wrap (TS) as both devices are provided in rectangular sheets that are several centimeters in size. The mechanical characteristics of the MacroPore Cardio-Wrap (TS) are substantially equivalent to the predicate devices with respect to mechanical strength as measured by tensile and suture pull out testing. In addition to physical characteristics, both the predicate device and the MacroPore Cardio-Wrap (TS) can be cut to specific shapes and sizes by the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2009

Macropore Biosurgery, Inc.
c/o Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
6740 Top Gun Street
San Diego, CA 92121

Re: K031785
Trade Name: MacroPore Cardio-Wrap (TS)
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: Class II (two)
Product Code: OMH
Dated: June 9, 2003
Received: June 10, 2003

Dear Mr. Kleinhenz:

This letter corrects our substantially equivalent letter of September 4, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: **MacroPore Cardio-Wrap (TS)**

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031785